## REMARKS

Upon entry of this amendment, claims 1-6, 8-15, 17-30, 43-54, 56-61, and 63-70 are pending in the application. Claim 62 has been canceled. Claims 1-6, 8-11, 15, 17-23, 24-30, 43-50, 54, 56-61, 64-67, and 68-70 have been amended. Support for the amendments can be found throughout the specification as-filed. No new matter has been added.

**Rejections under 35 USC § 112, second paragraph**

Claims 1-6, 8-15, 17-30, 43-54, and 56-70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. *See*, Office Action at pages 2-5.

Specifically, the Examiner indicates that in claim 1, it is not clear what is binding or in who or what diagnosing is being accomplished. *See*, Office Action at page 2. Claim 1 has been amended to recite "binding of said IgA ACCA in said sample" and "diagnosing Crohn's disease in said subject", as suggested by the Examiner. Applicants submit that claim 1 is clear and that this rejection should be withdrawn.

The Examiner states that in claim 2, it is unclear how a sample is an individual. *See*, Office Action at page 2. Claim 2 has been amended to require that the control reference level is a level from one or more individuals without Crohn's disease. Applicants submit that claim 2 is clear and that this rejection should be withdrawn.

The Examiner indicates that in claim 5, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 3. Claim 5 has been amended to recite that the subject is assessed as having Crohn's disease if the anti-Glc (β 1-3) Glc (β) antibody (ALCA) or the polysaccharide β-D (1-3) Glucan antibody

levels are elevated in the sample relative to a control reference level. Applicants submit that claim 5 is clear and that this rejection should be withdrawn.

According to the Examiner, in claim 6, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 3. Claim 6 has been amended to recite that the subject is assessed as having Crohn's disease if the ALCA and the polysaccharide β-D (1-3) Glucan antibody levels are elevated in the sample relative to a control reference level. Applicants submit that claim 6 is clear and that this rejection should be withdrawn.

The Examiner states that in claim 11, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 3. Claim 11 has been amended to recite that the subject is assessed as having Crohn's disease if the levels of each of the detected antibodies are elevated in the sample relative to a control reference level. Applicants submit that claim 11 is clear and that this rejection should be withdrawn.

The Examiner indicates that in claim 15, it is not clear which of the antibodies is "said" antibody. *See*, Office Action at page 3. Claim 15 has been amended to require determining an isotype of the anti-Glc (β 1-3) Glc (β) antibody or the anti-polysaccharide β-D (1-3) Glucan antibody in the sample. Applicants submit that claim 15 is clear and that this rejection should be withdrawn.

The Examiner states that claim 17 is redundant if ACCA was intended. *See*, Office Action at page 3. Claim 17 has been amended to recite that the anti-Glc (β 1-3) Glc (β) antibody or the anti-polysaccharide β-D (1-3) Glucan antibody in the sample is an IgA isotype antibody. Applicants submit that claim 17 is clear and that this rejection should be withdrawn.

According to the Examiner, in claim 19, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 3. Claim 19 has been amended to recite that the subject is assessed as having Crohn's disease if the levels of each of the detected antibodies are elevated in the sample relative to a control reference level. Applicants submit that claim 19 is clear and that this rejection should be withdrawn.

The Examiner states that in claims 20 and 21, it is not clear which of the antibodies is "said" antibody and that the relationship of "identified" to "detecting" is not clear. *See*, Office Action at page 3. Claim 20 has been amended to require that ACCA is detected with a fluorescent antibody. Claim 21 has been amended to require that ACCA is detected with an enzyme-linked immunoabsorbent assay (ELISA). Applicants submit that claims 20 and 21 are clear and that this rejection should be withdrawn.

The Examiner indicates that in claim 22, it is not clear what is binding or in who or what diagnosing is being accomplished. *See*, Office Action at page 3. Claim 22 has been amended to recite "binding of said ALCA in said sample" and "diagnosing Crohn's Disease in said subject", as suggested by the Examiner. Applicants submit that claim 22 is clear and that this rejection should be withdrawn.

According to the Examiner, in claim 24, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's Disease are not clear. *See*, Office Action at page 3. Claim 24 has been amended to recite that the subject is assessed as having Crohn's disease if the IgG anti-Man ($\alpha$ 1-3) Man ($\alpha$) antibody levels are elevated in the sample relative to a control reference level. Applicants submit that claim 24 is clear and that this rejection should be withdrawn.

The Examiner states that in claim 25, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's Disease are not clear. *See*, Office Action at page 3. Claim 25 has been amended to recite that the subject is assessed as having Crohn's disease if the IgG anti-Glc (β 1-3) Glc (β) antibody (ALCA) and the IgG anti-Man (α 1-3) Man (α) antibody (AMCA) levels are elevated in the sample relative to a control reference level. Applicants submit that claim 25 is clear and that this rejection should be withdrawn.

The Examiner indicates that in claim 26, the interrelationships of the steps to those of the independent claim are not clear, as diagnosis already requires ALCA. *See*, Office Action at page 3. Claim 26 has been amended to recite that the subject is assessed as having Crohn's Disease if the IgG anti-Mannan antibody (ASCA) or the IgA ASCA is elevated in the sample relative to a control reference level. Applicants submit that claim 26 is clear and that this rejection should be withdrawn.

According to the Examiner, in claim 30, it is not clear what is binding. *See*, Office Action at page 5. Claim 30 has been amended to recite "binding of said ALCA in said sample", as suggested by the Examiner. The Examiner also states that ASCA is not defined in claim 30. Claim 30 has been amended to recite "identifying a specific anti-Mannan antibody (ASCA)". The Examiner also indicates that improper Markush language is used to claim members of a group in claim 30. Claim 30 has been amended to require the "presence of at least one of said IgG ALCA, IgG ASCA, or IgA ASCA antibodies in said test sample" (emphasis added). Applicants submit that claim 30 is clear and that this rejection should be withdrawn.

According to the Examiner, in claim 43, it is unclear how a sample is an individual. *See*, Office Action at page 4. Claim 43 has been amended to recite that the control reference level is a

level from one or more individuals without Crohn's disease. Applicants submit that claim 43 is clear and that this rejection should be withdrawn.

The Examiner states that in claim 46, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 4. Claim 46 has been amended to recite that the subject is assessed as having Crohn's disease if the anti-GlcNAc (β 1-4) GlcNAc (β) antibody (ACCA) or the anti-polysaccharide β-D (1-3) Glucan antibody levels are elevated in the sample relative to a control reference level. Applicants submit that claim 46 is clear and that this rejection should be withdrawn.

The Examiner states that in claim 47, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 4. Claim 47 has been amended to recite that the subject is assessed as having Crohn's disease if the ACCA and the anti-polysaccharide β-D (1-3) Glucan antibody levels are elevated in the sample relative to a control reference level. Applicants submit that claim 47 is clear and that this rejection should be withdrawn.

The Examiner indicates that in claim 54, it is not clear which of the antibodies is "said" antibody. *See*, Office Action at page 4. Claim 54 has been amended to recite determining an isotype of the ALCA and the detected ACCA or the detected anti-polysaccharide β-D (1-3) Glucan antibody in the sample. Applicants submit that claim 54 is clear and that this rejection should be withdrawn.

The Examiner states that in claim 58, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 4. Claim 58 has been amended to recite that the subject is assessed as having Crohn's disease if the levels of each of the detected antibodies are elevated in the sample relative to a control

reference level. Applicants submit that claim 58 is clear and that this rejection should be withdrawn.

The Examiner states that in claims 59 and 60, it is not clear which of the antibodies is "said" antibody and that the relationship of "identified" to "detecting" is not clear. *See*, Office Action at page 4. Claim 59 has been amended to require that ALCA is detected with a fluorescent antibody. Claim 60 has been amended to require that ALCA is detected with an enzyme-linked immunoabsorbent assay (ELISA). Applicants submit that claims 59 and 60 are clear and that this rejection should be withdrawn.

According to the Examiner, in claim 61, the interrelationships of the steps to those of the independent claim and the diagnosis of Crohn's disease are not clear. *See*, Office Action at page 4. Claim 61 has been amended to recite that the subject is assessed as having Crohn's disease if the levels of each of the detected antibodies are elevated in the sample relative to a control reference level. Applicants submit that claim 61 is clear and that this rejection should be withdrawn.

The Examiner indicates that claim 62 is redundant and does not appear to further limit the subject matter of claim 1. Claim 62 has been canceled. This rejection should be withdrawn.

The Examiner indicates that in claims 64-66, it is not clear what is binding or in who or what diagnosing is being accomplished. *See*, Office Action at pages 4-5. Claim 64 has been amended to recite "binding of said ASCA in said sample" and "diagnosing Crohn's disease in said subject", as suggested by the Examiner. Claim 65 has been amended to recite "binding of said ALCA in said sample" and "diagnosing Crohn's disease in said subject", as suggested by the Examiner. Claim 66 has been amended to recite "binding of said AMCA in said sample" and

"diagnosing Crohn's disease in said subject", as suggested by the Examiner. Applicants submit that claims 64-66 are clear and that these rejections should be withdrawn.

According to the Examiner, in claim 67, it is not clear what in the sample is binding. *See*, Office Action at page 5. Claim 67 has been amended to recite "binding of said ACCA in said sample", "binding of said ALCA in said sample", "binding of said ASCA in said sample", and "binding of said AMCA in said sample", as suggested by the Examiner. Applicants submit that claim 67 is clear and that this rejection should be withdrawn.

For the reasons articulated above, Applicants submit that the pending claims are clear and that the rejections under 35 U.S.C. § 112, second paragraph should be withdrawn.

## CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Such action is respectfully requested. The Commissioner is authorized to charge any fees that may be due to Deposit Account No. 50-0311, Reference No. 25681-502 P.

Respectfully submitted,

/IABeattie/

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Date: March 18, 2009